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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,694	01/23/2004	Hyeong-sop Shim	YPL-0076	7659

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EXAMINER	
SMITH, CAROLYN L	
ART UNIT	PAPER NUMBER
1631	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,694	SHIM ET AL.	
	Examiner	Art Unit	
	Carolyn L. Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☒ Claim(s) *5,8 and 9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *030305, 042904*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of Group I (claims 1-15), filed 1/19/07, is acknowledged. Claim 16 is withdrawn from consideration as being drawn to a non-elected Group.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to a robust genotyping method using DNA chip and DNA chip used therein, whereas in contrast the elected claims are specifically directed to a genotyping method.

Claims herein under examination are 1-15.

Claim Objections

Claims 5, 8, and 9 are objected to because of the following minor informalities:

Claim 5 (lines 4-5) recites "an input vector that *are* calculated" which is grammatically awkward.

Claims 8 (lines 8-9) and 9 (line 9) recite "a independence" which is grammatically incorrect.

Appropriate correction is requested.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 and 17 of copending Application No. 11/019011 (referred to as '011). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The specification of the instant application (page 1, lines 11-12 and 17-21; page 3, paragraph 4; page 10, last paragraph) recites probes that perfectly matches a mutant type or wild type gene (discriminating) for each mutation site on a DNA chip (amplicons), probes at mutation and non-mutation sites, and identifying whether a nucleic acid is a wild type or mutant type. Therefore, the genotyping method comprising using a DNA chip with an optimal probe set of claim 1 of '011 anticipates instant claim 1. Claims 2-14 and 17 of '011 anticipate instant claims 2-15, respectively. Therefore, instant claims 1-15 are generic to claims 1-14 and 17 of copending Application No. 11/019011.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 1 (line 1), 4 (lines 4 and 9), 5 (line 2), 6 (lines 7 and 11), 7 (line 2), 8 (lines 3, 4 and 8-9), 9 (lines 3, 5, 8, 9), and 11 (line 7) recite the term "using" or "used" which is vague and indefinite. It is unclear what step or steps are intended to by encompassed by the "using" and "used" terminology. Clarification of this issue via clearer claim wording is requested. Claims 2-3, 10,and 12-15 are also rejected due to their dependency from claim 1.

Claims 1 (lines 1-2), 4 (lines 3-4) recite "an optimal probe pair of a wild type-perfect match probe and a mutant type-perfect match probe" or "probe pairs of a wild type-perfect match probe and a mutant type-perfect match probe" which is vague and indefinite. It is unclear if the probe pair is intended to be a probe pair comprising a wild type-perfect match probe and a mutant type-perfect match probe or a probe pair of a wild type-perfect match probe as well as an optimal probe pair of a mutant type-perfect match probe. Clarification of this issue via clearer

claim wording is requested. Claims 2-3 and 5-15 are also rejected due to their dependency from claim 1.

Claim 1 (line 3) recites "for each mutation site" which is vague and indefinite. It is unclear from what is each mutation site. Clarification of this issue via clearer claim wording is requested. Claims 2-15 are also rejected due to their dependency from claim 1.

Claims 2 (line 2) and 3 (line 4) recite "each mutation site of the DNA chip" which is vague and indefinite. While DNA may have a mutation site, it is unclear what would be a mutation site of a DNA chip. Clarification of this issue via clearer claim wording is requested.

Claim 4 (line 12) recites the limitation "the target nucleic acid". There is insufficient antecedent basis for this limitation in the claim. While there is previous mention of a "standard nucleic acid", there is no previous mention of a "target nucleic acid". Clarification of this issue via clearer claim wording is requested.

Claim 6 (lines 4-6) recites "calculating the ratio between the hybridization intensity of the standard nucleic acid to the wild type-perfect match probe and the hybridization intensity of the standard nucleic acid to the mutant type-perfect match [sic]" which is vague and indefinite. It is unclear if this is intended to mean a ratio between the hybridization intensity of the standard nucleic acid to the wild type-perfect match probe and a ratio between the hybridization intensity of the standard nucleic acid to the mutant type-perfect match probe OR only one ratio with the numerator being the hybridization intensity of the standard nucleic acid to the wild type-perfect match probe and the denominator being the hybridization intensity of the standard nucleic acid to the mutant type-perfect match probe. If only one ratio is intended, then "the calculated ratios" in

line 7 lacks proper antecedent basis. Clarification of this issue via clearer claim wording is requested. Claims 7-10 are also rejected due to their dependency from claim 6.

Claims 6 and 11 recite the limitation "the mutant type-perfect match" in line 6 of each. There is insufficient antecedent basis for this limitation in the claim. While there is previous mention of a mutant type-perfect match probe, there is no previous mention of a "mutant type-perfect match". Clarification of this issue via clearer claim wording is requested. Claims 7-10 and 12-14 are also rejected due to their dependency from claim 6.

Claim 8 recites the limitation "the products" in line 3. There is insufficient antecedent basis for this limitation in the claim as there is no previous mention of products. Clarification of this issue via clearer claim wording is requested.

Claim 8 recites the limitation "the vector" in line 4. There is insufficient antecedent basis for this limitation in the claim. In claim 6, from which claim 8 depends, there is a set of vectors. Therefore, it is unclear which particular vector is being referred to in claim 8. Clarification of this issue via clearer claim wording is requested.

Claims 8 (line 8) and 9 (line 8) recites the limitation "the ratio components". There is insufficient antecedent basis for this limitation in the claim. In claim 6, from which claims 8 and 9 depend, there is only previous mention of a single ratio component, not plural components. Clarification of this issue via clearer claim wording is requested.

Claim 9 (lines 2-3) recites "the larger" and "the selected larger" which is vague and indefinite. It is unclear what parameters and to what degree these parameters must be met to be considered "larger". Clarification of this issue via clearer claim wording is requested.

Claim 11 (lines 4-6) recites "calculating the ratio between the hybridization intensity of the target nucleic acid to the wild type-perfect match probe and the hybridization intensity of the target nucleic acid to the mutant type-perfect match [sic]" which is vague and indefinite. It is unclear if this is intended to mean a ratio between the hybridization intensity of the target nucleic acid to the wild type-perfect match probe and a ratio between the hybridization intensity of the target nucleic acid to the mutant type-perfect match probe OR only one ratio with the numerator being the hybridization intensity of the target nucleic acid to the wild type-perfect match probe and the denominator being the hybridization intensity of the target nucleic acid to the mutant type-perfect match probe. If only one ratio is intended, then "the calculated ratios" in line 7 lacks proper antecedent basis. Clarification of this issue via clearer claim wording is requested. Claims 12-14 are also rejected due to their dependency from claim 11.

Claim 11 recites the limitation "the hybridization intensity" in line 4. There is insufficient antecedent basis for this limitation in the claim. While there previous mention of hybridization data, there is no previous mention of any hybridization intensity. Clarification of this issue via clearer claim wording is requested. Claims 12-14 are also rejected due to their dependency from claim 11.

Claims 12 (lines 2 and 5) and 13 (lines 2 and 5) recite the limitation "the posterior probabilities" and "the greater posterior probability". There is insufficient antecedent basis for this limitation in the claim as there is no previous mention of this limitation. It is also unclear what parameters are required and to what degree these parameters must be met to be considered "greater". Clarification of this issue via clearer claim wording is requested.

Claim 13 recites the limitation "the reliability requirement" in the last two lines. There is insufficient antecedent basis for this limitation in the claim. While there previous mention of reliability, there is no previous mention of a reliability requirement. Clarification of this issue via clearer claim wording is requested.

Claim 15 recites "cross-hybridization data of the probe pair for each mutation site" which is vague and indefinite. It is unclear to what is being cross-hybridized. It is also unclear from what is the mutation site. Clarification of this issue via clearer claim wording is requested.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Mack (US 6,303,301 B1).

Mack discloses methods for mapping regulatory relationship among genes by massive parallel monitoring gene expression (abstract) and using a p53 genotyping array and immobilized polymer synthesis (col. 10, second paragraph and col. 30, second paragraph) and an optimum subset of probes for each gene (col. 19, first paragraph) for wild-type and mutant perfect matches (col. 6, last paragraph and col. 29, second and fifth paragraphs) in a region containing a mutation (col. 4, second to last paragraph), as stated in instant claim 1. Mack discloses mutations in p53

gene, detecting all mutations, and finding potential mutations (col. 29, fourth and fifth paragraphs; col. 30, second paragraph) as well as G to A mutation in p53 gene, detecting heterozygous mutations in regulatory genes, and allele specific probes for over 300 characterized hotspot p53 mutations (col. 31, first and fourth paragraphs; col. 38, last paragraph). Mack discloses using arrays with at least 20 probe pairs for each region being monitored that yield the best discrimination between perfect match and single base mismatch hybridization (col. 34, second paragraph) which represents at least two optimal probe pairs immobilized for each mutation site of the DNA chip, as stated in instant claim 2. Mack discloses massive parallel screening using an array of probes, using same primers, and probe design (col. 13, last paragraph to col. 14, first paragraph; col. 15, fifth paragraph; col.16, last two paragraphs) as well as a genotyping method of wild-type and mutant type experiments arranged side by side and adjacent to each other (Figure 4), as stated in instant claim 3. Mack discloses using a genotyping algorithm using data obtained from array hybridization patterns of an experimental sample (unknown) relative to a wild-type reference (identified standard); performing base identification of nucleotide changes between the sample and reference via strongest signals from probes containing the substitution base and footprint analysis; as well as correlating expressions of targets with mutants (col. 39, second and third paragraphs), as stated in instant claim 5. Mack discloses correcting results based on cross-hybridization data (col. 18, second paragraph; col. 24, last paragraph to col. 25, first paragraph; col. 34, second paragraph), as stated in instant claim 15.

Thus, Mack anticipates the limitations in claims 1-3, 5, and 15.

Conclusion

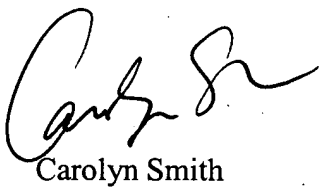
No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, can be reached on (571) 272-0781.

February 27, 2007



Carolyn Smith
Examiner
AU 1631